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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,628	12/01/2000	Katherine Armstrong	50,597	4194

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,628

Applicant(s)

ARMSTRONG ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-5 and 7-8 have been cancelled, claims 6 and 9-11 have been amended, and claims 12-16 have been added, as requested in Paper No. 4, filed 16 September 2002. Claims 6 and 9-16 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

3. The rejection of claims 1-2, 4-5 and 7-11 under 35 U.S.C. 102(e) as being anticipated by Lappegard et al (US Patent 6,225,529, filed August, 1998) is WITHDRAWN in light of cancellation of those claims and presentation of new claims that are not drawn to a MIP synthase promoter comprising 20 contiguous nucleic acids of SEQ ID NO:3.
4. The rejection of claims 1-2 and 5 under 35 U.S.C. 102(b) as being anticipated by Lopes et al (1991, Nucleic Acids Res. 19:1687-93) is WITHDRAWN in light of cancellation of those claims and presentation of new claims that are not drawn to a MIP synthase promoter that would hybridize to SEQ ID NO:3.

Claim Objections

5. Claims 12-13 and 15-16 are objected to because of the following informalities:
Claims 13 and 16 start with an improper article.
Claim 15 has an improper article before "DBA" in line 5.
In claim 12, --wherein-- should be inserted before "said" in line 3.

Claim Rejections - 35 USC § 112

6. Claims 9-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter of bases 7-2064 of SEQ ID NO:3, does not reasonably provide enablement for promoters that comprise 200 consecutive base pairs of bases 7-2064 of SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 March, 2002, as applied to claims 1-5 and 7-11. Applicant's arguments filed 16 September 2002 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids comprising 200 consecutive base pairs of bases 7-2064 of SEQ ID NO:3 and that function as promoters, DNA constructs comprising those nucleic acids, plants transformed with those DNA constructs, and a method of using an the promoter to express a heterologous nucleic acid in a plant.

The instant specification, however, only provides guidance for the isolation of the MIP synthase cDNA from maize embryo cDNA by PCR with primers based on the yeast gene sequence and the use of the cDNA to probe a maize cDNA library (Example 1), analysis of MIP synthase expression patterns in maize seed (Example 2), cloning of the flanking sequences from maize genomic DNA and their sequencing (Example 3), and operable linkage of the *gus* coding sequence to the full-length version of this isolated MIP synthase promoter (bases 7-2064 of SEQ ID NO:3) and in transient expression of GUS in maize embryos and stable expression in maize callus and plants (examples 3-7).

The specification fails to provide guidance for which 200 base pair long regions of bases 7-2064 of SEQ ID NO:3 would function as promoters.

Given the claim breath and lack of guidance, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of nucleic acids comprising MIP synthase promoters or fragments (including those as small as 20 nucleotides) or variants of those nucleic acids. Making all possible 200 consecutive nucleotide fragments of bases 7-2064 of SEQ ID NO:3 would require generation and analysis of 1858 fragments. Thus, without guidance, undue experimentation would be required to generate and analyze these fragments and variants.

Therefore, the specification is not enabled for a multitude of nucleic acids comprising 200 consecutive base pairs of bases 7-2064 of SEQ ID NO:3 and that function as promoters, DNA constructs comprising those nucleic acids, plants transformed with those DNA constructs, and a method of using an the promoter to express a heterologous nucleic acid in a plant.

Applicant urges that the claims have been amended to overcome the rejection (response pg 3). This is not found persuasive because the specification does not teach nucleic acids that comprise 200 consecutive base pairs of bases 7-2064 of SEQ ID NO:3 and that function as promoters.

7. Claims 9-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 March, 2002, as applied to claims 1-5 and 7-11. Applicant's arguments filed 16 September 2002 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to overcome the rejection (response pg 3). This is not found persuasive because the specification does not describe nucleic acids that comprise 200 consecutive base pairs of bases 7-2064 of SEQ ID NO:3 and that function as

promoters. The specification only describes a promoter that comprises bases 7-2064 of SEQ ID NO:3.

8. Claims 6 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 6 lacks antecedent basis for the limitation "the expression cassette of claim 12.

Claim 9 lacks antecedent basis for the limitation "the method of claim 13", as claim 13 is drawn to an isolated DNA molecule. For purposes of examination, claim 9 was treated as though it were dependent upon claim 16. Such treatment does not relieve Applicant from responding to this rejection.

Claim 14 lacks antecedent basis for the limitation "the DNA sequence of claim 12" in line 2.

Claims 14 and 15 are indefinite in their recitation of "and, as promoter,". It is suggested that claim 14 be amended to replace "and, ... acid sequence" with --operably linked to the DNA molecule of claim 12--. A suggestion for amending claim 15 is below.

Claim 15 lacks antecedent basis for the limitations "DNA sequence of claim 12" in line 5 and "said heterologous nucleic acid" in line 6. It is suggested that the phrase "a DNA construct ... nucleic acid", starting in line 4 and ending in line 6, be replaced with --the DNA construct of claim 14--.

Claim 16 lacks antecedent basis for the limitations "said heterologous nucleic acid sequence" in lines 2-3 and "said operably linked promoter" in line 3. It is suggested that the phrase "said heterologous ... promoter" be replaced with --the DNA construct--.

9. Claims 6 and 9-16 are free of the prior art, given the failure of the prior art to teach or suggest a nucleic acid of bases 7-2064 of SEQ ID NO:2 or comprising at least 200 consecutive bases of bases 7-2064 of SEQ ID NO:2.

10. Claim 13 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
November 27, 2002



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